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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Makoto Noami

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WENDEROTH, LIND & PONACK, L.L.P.

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EXAMINER

BUIE, NICOLE M

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,739	Applicant(s) NOAMI ET AL.	
	Examiner NICOLE M. BUIE	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20060210/20060503/20080915</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 12 recite the limitation "partially hydrolyzed polyvinyl alcohol". There is insufficient antecedent basis for this limitation in the claim. For the purpose of this Office Action, "partially hydrolyzed polyvinyl alcohol" will be treated as "polyvinyl alcohol".

Claim 12 recites the limitations "methyl methacrylate" and "acrylic acid". There is insufficient antecedent basis for this limitation in the claim. For the purpose of this Office Action, "methyl methacrylate" and "acrylic acid" will be treated as polymerizable vinyl monomers.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Hoshi et al. (US 2003/0166763).

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Regarding claims 1-3, 5, 6, and 12, Hoshi et al. discloses a resin composition, characterized in that said composition is obtained by copolymerizing a polyvinyl alcohol having an average polymerization degree of 2000 or less (Synthesis Examples 1-4), wherein specific average polymerization degrees of “500” is disclosed in Synthesis Examples 1-4 (as compared to 1300 or less, or 900 or less, or 200-600 as required by said claim), and two polymerizable vinyl monomers (i.e. methacrylic acid and methyl methacrylate or acrylic acid and methyl methacrylate) in a weight ratio of each is disclosed in Table 4, wherein the quantities of each fall squarely in the specified ranges.

Regarding claim 4, Hoshi et al. discloses a resin composition wherein a polyvinyl alcohol is a partially hydrolyzed polyvinyl alcohol ([0025], Examples 1-4).

Regarding claims 7-9, Hoshi et al. discloses a composition wherein an unsaturated carboxylic acid is acrylic acid, methacrylic acid, fumaric acid, maleic acid, or itaconic acid, or salts thereof ([0029], [0030]), and an unsaturated carboxylic acid ester is methyl methacrylate, methyl acrylate, ethyl methacrylate, ethyl acrylate, butyl methacrylate, butyl acrylate, isobutyl methacrylate isobutyl acrylate, cyclohexyl methacrylate, cyclohexyl acrylate, 2-ethylhexyl methacrylate, 2-ethylhexyl acrylate, hydroxyethyl methacrylate, hydroxyethyl acrylate, an ester of polyethylene glycol and methacrylic acid, an ester of polyethylene glycol and acrylic acid, or an ester of polypropylene glycol and acrylic acid [0031].

Regarding claims 10 and 11, Hoshi et al. discloses a composition wherein the weight ratio of acrylic acid and methyl methacrylate in the copolymerization is 0.25 (5/20), 0.43 (7.5/17.5) (See Examples E-2001 to E-2006 of Table 2 and Examples E-4001 to E-4006 of Table 4).

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Regarding claim 13-15, Hoshi et al. discloses a coating agent comprising a resin composition for medicines, animal drugs or foods ([0045]-[0048]).

Claim 16 is rejected under 35 U.S.C. 102(a) as being anticipated by Hoshi et al. (US 2003/0166763) as applied to claim 1 above and in further in view of evidence of Saliba et al. (US 2003/0059649).

Regarding claim 16, Hoshi et al. discloses a binder comprising a resin composition wherein a polyvinyl alcohol copolymers are binders in coating compositions as evidenced by Saliba et al. [0043].

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Saiden Chemical Industry Co., Ltd. (JP 2002-105383, see machine translation for citation).

Regarding claims 1-3 and 12, JP '383 discloses a resin composition, characterized in that said composition is obtained by copolymerizing a polyvinyl alcohol having an average polymerization degree of 500-2000 [0016] (as compared to 1300 or less, 900 or less, or 200-600 as required by said claim) and at least one or more polymerizable vinyl monomer(s) in a weight ratio of approximately 2:5 to 2:1 [0018] (as compared to 6:4 to 9:1 as required by said claim).

Regarding claim 4, JP '383 discloses a composition wherein a polyvinyl alcohol is a partially hydrolyzed polyvinyl alcohol (The degree of saponification is 93-99.9 mole%.) [0016].

Regarding claim 5, JP'383 discloses a composition wherein a polymerizable vinyl monomer is an unsaturated carboxylic acid (i.e. acrylic acid) (Example 4), an unsaturated carboxylic acid ester [0011], an unsaturated amide [0013], or an aromatic vinyl [0012].

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Regarding claims 6-9, JP '383 discloses a composition wherein a composition is obtained by copolymerizing an unsaturated carboxylic acid (i.e. acrylic acid, methacrylic acid, crotonic acid, maleic acid, itaconic acid) [0013] and an unsaturated carboxylic acid ester (i.e. methyl methacrylate, ethyl methacrylate, butyl methacrylate, cyclohexyl methacrylate) ([0011]).

Regarding claim 10, JP '383 discloses a composition wherein the weight ratio of acrylic acid and methyl methacrylate in the copolymerization is 0.5:9.5 ([0028]) (as compared to 3:7 to 0.5:9.5 as required by said claim).

Regarding claims 11, JP '383 discloses a composition characterized in that a composition is obtained by copolymerizing a polyvinyl alcohol having an average polymerization degree of 500-2000 [0016] (as compared to 300 to 500 as required by said claim).

Regarding claim 13, JP '383 discloses a coating agent comprising a resin composition [0001].

Regarding claim 14, JP '383 discloses a coating agent for drugs or food [0002].

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Sainen Chemical Industry Co., Ltd. (JP 2002-105383, see machine translation for citation) and in further view of evidence of Saliba et al. (US 2003/0059649).

Regarding claim 16, JP '383 discloses a binder comprising a resin composition wherein a polyvinyl alcohol copolymers are binders in coating compositions as evidenced by Saliba et al. [0043].

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sainen Chemical Industry Co., Ltd. (JP 2002-105383, see machine translation for citation) as applied to claim 1 above in view of Keith et al. (US 4,432,965).

Regarding claim 15, JP '383 discloses a composition as shown above in claim 1.

However, JP '383 does not disclose a medicine, an animal drug, an agricultural chemical, a fertilizer or a food which is coated with a coating agent. Keith et al. teaches drugs coated with polyvinyl alcohol compositions (C11-21). JP '383 and Keith et al. are analogous art concerned with the same field of endeavor, namely polyvinyl alcohol compositions for coating drugs. It would have been obvious to one of ordinary skill in the art at the time of invention to coat drugs

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of Keith et al. with a composition of JP '383, and the motivation to do so would have been as Jordan et al. suggests adjust the rate of release of the drug (C1/L36-53).

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saiden Chemical Industry Co., Ltd. (JP 2002-105383, see machine translation for citation).

Regarding claims 17 and 18, JP '383 discloses a resin composition, characterized in that said composition is obtained by copolymerizing a polyvinyl alcohol having an average polymerization degree of 500-1,000 [0016] with a specific polymerization degree of 500 [0025] (as compared to 900 or less as required by said claim), and at least one or more polymerizable vinyl monomers such as an unsaturated carboxylic acid (i.e. acrylic acid, methacrylic acid, crotonic acid, maleic acid, itaconic acid) [0013] and an unsaturated carboxylic acid ester (i.e. methyl methacrylate, ethyl methacrylate, butyl methacrylate, cyclohexyl methacrylate) ([0011] in a weight ratio of approximately 2:5 to 2:1 [0018] (as compared to 6:4 to 9:1 as required by said claim), and a copolymer of a polyvinyl alcohol having an average polymerization degree of 1,000-2,000 [0016] with a specific average polymerization degree of 1700 [0025] (as compared to 1500 or 1700 as required by said claim) with comonomers, such as methacrylate esters, aromatic vinyl system, monomer which has functional groups (i.e. methacrylic acid, crotonic acid, itaconic acid) ([0011]-[0013]).

Regarding the method limitations, the examiner notes that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated *in Thorpe*, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a

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product does not depend on its method of production. *In re Pilkington*, 411 F. 2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process). See MPEP § 2113.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saiden Chemical Industry Co., Ltd. (JP 2002-105383, see machine translation for citation) as applied to claims 17 and 18 above, and further in view of Keith et al. (US 4,432,965).

Regarding claims 19 and 20, JP '383 discloses a resin composition as shown above in claims 17 and 18. JP '383 discloses a packing material for drugs [0002].

However, JP '383 does not disclose a coating agent for tablets or granules. Keith et al. teaches a tablet coated with a polyvinyl alcohol composition (Abstract, C1/L11-21). JP '383 and Keith et al. are analogous art concerned with the same field of endeavor, namely polyvinyl alcohol compositions for coating drugs. It would have been obvious to one of ordinary skill in the art at the time of invention to coat drugs of Keith et al. with a composition of JP '383, and the motivation to do so would have been as Jordan et al. suggests adjust the rate of release of the drug (C1/L36-53).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE M. BUIE whose telephone number is (571)270-3879. The examiner can normally be reached on Monday-Thursday with alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on (571)272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. M. B./
Examiner, Art Unit 1796
10/9/2008

/Marc S. Zimmer/
Primary Examiner, Art Unit 1796